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IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF ALABAMA  
NORTHERN DIVISIONDEBRA P. HACKETT, CLK  
U.S. DISTRICT COURT  
MIDDLE DISTRICT ALACLARICE HARE,  
Plaintiff,

vs.

G.D. SEARLE, LLC (hereinafter  
"Searle") a subsidiary of PHARMACIA  
CORPORATION, (hereinafter  
"Pharmacia"), a Foreign Corporation;  
MONSANTO COMPANY; PFIZER  
INC., et al,

Defendants.

CIVIL ACTION NO.

2:05cv476

**ANSWER AND DEFENSES OF DEFENDANTS PHARMACIA CORPORATION,  
G.D. SEARLE LLC AND PFIZER INC. TO PLAINTIFF'S COMPLAINT**

Defendants Pharmacia Corporation (formerly "1933 Monsanto," see Paragraph 6, and improperly captioned in Plaintiff's Complaint as Monsanto Company), G.D. Searle, LLC and Pfizer Inc. (collectively "Defendants"), answer plaintiff's complaint in this action as follows:

**PRELIMINARY STATEMENT**

In November 2001, Bextra® was approved, as labeled, by the United States food and Drug Administration ("FDA") as a prescription medication. At times Bextra® was advertised, promoted, marketed, and distributed in the United States by Defendants or one of their subsidiaries to be prescribed by healthcare providers who are authorized by law to prescribe medications in accordance with their approval by the FDA.

In April 2003 Pfizer merged with Pharmacia and the responsibilities for Bextra® were reallocated. G. D. Searle LLC (Searle) is presently a wholly owned third tier subsidiary of Pharmacia which in turn is a wholly owned subsidiary of Pfizer.

This preliminary statement is incorporated by reference in its entirety in response to each and every paragraph of plaintiff's complaint.

**ANSWERING:**  
**GENERAL ALLEGATIONS**

1. No response is required.

2.-3. Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in these paragraphs, and therefore deny the same.

4. Defendants admit that Searle is a wholly-owned subsidiary of Pharmacia Corporation, which is in turn a wholly-owned subsidiary of Pfizer. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Skokie, Illinois and is not registered to do business in Alabama. Defendants further admit that Searle can be served at the designated address. Defendants admit that at times Searle has manufactured, marketed, sold and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA.

5. Defendants admit that Pharmacia is a Delaware corporation. Defendants admit that Pharmacia is registered to do business in Alabama with a registered agent for service of process at the address alleged. Except as stated herein, defendants deny the allegations of Paragraph 5.

6. Defendants state in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. Defendants state that Pharmacia Corporation (formerly known as 1933 Monsanto) is a Delaware Corporation. On February 9, 2000, Monsanto Ag Company was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever designed, produced, manufactured, sold, resold or distributed Bextra®, defendants are therefore assuming that the 2000 Monsanto is not a party in this matter. Except as stated herein, Defendants deny the allegations of Paragraph 6.

7. Defendants admit that Pfizer is a Delaware corporation. Defendants admit that Pfizer is registered to do business in Alabama with a registered agent for service of process at the address alleged. Defendants admit that at times they marketed, distributed and sold Bextra® throughout the United States. Except as stated herein, defendants deny the allegations of Paragraph 7.

8. Defendants state that this case is properly removed to the U.S. District Court for the Middle District of Alabama.

9. Defendants assert that the complaint satisfies the jurisdictional amount of federal diversity jurisdiction but have insufficient information or knowledge to form a

belief as to the truth of the allegations contained in these paragraphs, and therefore deny the same.

10. Defendants state that Bextra® is a prescription medication which is approved by the FDA for the indications described in its labeling.

11. Denied.

ANSWERING:  
COUNT I

12. Defendants state that Bextra® is a prescription medication which was at all times relevant to this suit approved by the FDA for use consistent with its prescribing information. Defendants admit that at times they manufactured, marketed, and distributed Bextra® in the United States to be prescribed by healthcare providers who are authorized by law to prescribe medications in accordance with their approval by the FDA. Except as stated herein, defendants deny the allegations contained in Paragraph 12.

13. Denied.

14. No response is required.

15. Defendants are without sufficient information to admit or deny the allegations contained in this paragraph.

16. No response is required.

17. Defendants admit that at times they manufactured, marketed, and distributed Bextra® in the United States to be prescribed by healthcare providers who are authorized by law to prescribe medications in accordance with their approval by the FDA. Except as stated herein defendants deny the allegations of Paragraph 17.

18. Denied.

19. No response is required.

20. Defendants incorporate by reference their response to the prior paragraphs as if set forth herein.

21. Denied.

22. Defendants state that these allegations are conclusions of law and hence require no response. Except as stated herein these allegations are denied.

23-28 Denied as to these paragraphs and each of the subparts thereof.

29. Defendants incorporate by reference their responses to the prior paragraphs as if fully set forth herein.

30-37. Denied as to these paragraphs and each of the subparts thereof.

38. Defendants incorporate by reference their responses to the prior paragraphs as if fully set forth herein.

39. Denied.

40-41. Defendants are without sufficient information to either admit or deny the allegations of Paragraphs 40-41 and hence deny them.

42. Defendants state that these allegations are conclusions of law and hence require no response. Except as stated herein these allegations are denied.

43-48. Denied.

49. Defendants incorporate by reference their responses to the prior paragraphs as if fully set forth herein.

50. Defendants admit to advertising Bextra® directly to consumers. Except as stated herein defendants deny the allegations contained in Paragraph 50.

51. Defendants admit only that its sales representatives detailed Bextra® to physicians consistent with FDA approved prescribing information. Except as stated herein, defendants deny the allegations contained in Paragraph 51.

52-55. Denied.

56. Defendants incorporate by reference their responses to the prior paragraphs as if fully set forth herein.

57-59. Defendants state that these allegations are conclusions of law and hence require no response. Except as stated herein these allegations are denied.

60. Defendants are without sufficient information to either admit or deny the allegations of this paragraph and hence deny them.

61-67. Denied as to these paragraphs and each subpart thereof.

68. Defendants incorporate by reference their responses to the prior paragraphs as if fully set forth herein.

69-82. Denied as to these paragraphs and each subpart thereof.

83. Defendants incorporate by reference their responses to the prior paragraphs as if fully set forth herein.

84-97. Denied as to these paragraphs and each subpart thereof.

#### DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to defendants in this matter. Defendants therefore assert the

following defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, defendants will withdraw any of these defenses as may be appropriate.

#### **FIRST DEFENSE**

The complaint fails to state a claim against defendants upon which relief can be granted.

#### **SECOND DEFENSE**

Plaintiff's claims may be barred by the applicable state of limitations or by the equitable doctrines of laches and estoppel.

#### **THIRD DEFENSE**

Plaintiff's injuries and damages, if any, were solely caused by the acts or omissions, abuse or misuse, negligence or fault otherwise, of third persons or parties over whom defendants had no control or right to control and whose actions are not, therefore, imputable to defendants.

#### **FOURTH DEFENSE**

Plaintiff's injuries and damages, if any, were proximately caused by the negligence or fault of plaintiff, or persons or parties whose identities are unknown at this time, which comparative negligence or fault is sufficient to proportionately reduce plaintiff's recovery or to bar it.

## FIFTH DEFENSE

Plaintiff's injuries, if any, were due to an allergic, idiosyncratic or idiopathic reaction to Bextra®, or by an unforeseeable illness, unavoidable accident, or pre-existing condition, without any negligence or culpable conduct by defendants.

## SIXTH DEFENSE

Plaintiff failed to exercise reasonable care and diligence to mitigate their injuries and damages, if any.

## SEVENTH DEFENSE

Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts §402A, Comment K.

## EIGHTH DEFENSE

Bextra® is safe when used as directed, and defendants reasonably assumed that its warnings would be read and heeded; therefore, Bextra® is neither defective nor unreasonably dangerous pursuant to Restatement (Second) of Torts §402A, Comment J.

## NINTH DEFENSE

Bextra® falls under the auspices of the Food, Drug and Cosmetic Act and regulations promulgated by the Food and Drug Administration and plaintiff's claims have been preempted under the Supremacy Clause of the U.S. Constitution. Alternatively, defendants are entitled to a presumption that Bextra® is not defective or unreasonably dangerous and that its labeling is adequate.

#### TENTH DEFENSE

Bextra® and defendants' actions conformed to the state of the art of medical and scientific knowledge at all times relevant to this lawsuit and/or Bextra® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability §4.

#### ELEVENTH DEFENSE

Defendants aver that Bextra® possesses no characteristic which renders it unreasonably dangerous in a reasonably anticipated use by a person.

#### TWELFTH DEFENSE

Defendants satisfied their duty to warn under the learned intermediary doctrine and plaintiff's claims are therefore barred.

#### THIRTEENTH DEFENSE

Plaintiff's allegations of fraud, deceit, and fraudulent misrepresentations are not stated with the degree of particularity required by F.R.C.P. 9(b) and should be dismissed.

#### FOURTHEENTH DEFENSE

To the extent that plaintiff relies upon any theory of breach of warranty, her claims are barred because defendants did not make or breach any express or implied warranties, further, plaintiff failed to give reasonable notice to defendants of an alleged breach or breaches of warranty as required bylaw.

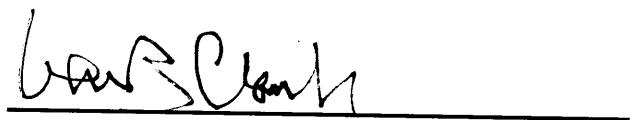
#### FIFTEENTH DEFENSE

Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damages awards which arise under the United States Constitution

and decision of the United States Supreme Court, or the Alabama Constitution, statutes and decisions of the Alabama courts.

JURY DEMAND

Defendants demand a trial by jury on all issues so triable.



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Pharmacia Corporation and  
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OF COUNSEL:

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CERTIFICATE OF SERVICE

I hereby certify that I have served a copy of the above pleading upon all counsel of record by placing a copy of same in the United States Mail on this the 20 day of May, 2005:

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